K033691

DEC 1 9 2003

Appendix 6

510(k) Summary of Safety and Effectiveness
November 22, 2003

A. GENERAL INFORMATION

Company Name and Address:

Sponsor/Manufacturer:	Promedon S.A.
Address:	Av. Hipolito Yrigoyen 388-PB X5000JHQ – Cordoba Cordoba, Argentina
Telephone:	011-54-351-424 6026
Fax:	011-54-351-424 6025
Contact Individual:	Marcelo Olmedo

Device Name	
Proprietary Name:	SAFYRE VS and SAFYRE T
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

Establishment Registration Number

Manufacturing Site:	Promedon S.A. Hipolito Yrigoyen 388 – PB X5000JHQ Cordoba Argentina Establishment Registration Number - 9680698

B. Identification of Predicate or Legally Marketed Device

- SAFYRE Sling System – K020007

C. Device Description

PROMEDON's Slings, SAFYRE VS and SAFYRE T, are manufactured with biocompatible silicone elastomers and polypropylene. Each sling is a permanent implant and is offered as a single use sterile product. Safyre consists of a monofilament polypropylene mesh between two silicone columns that are made of multiple cone-shaped soft tissue anchors. These units are the basis of the self anchoring system. The polypropylene mesh lies on the mid-urethra and the interconnective tissue grows among its pores, between the vaginal flap and the urethra, which leads to integration of the implant without a loss of vascularization between the bladder and the vagina. The two columns are fixed to the abdominal fascia or the obturator muscle. This self anchoring is

enough to keep the sling in its place when there is an important muscular activity, such as coughing or other strains.

SAFYRE VS consists of a sling and a pair of single-use surgical instruments to facilitate its vaginal or suprapubic implantation ; while SAFYRE T is made up of the same sling, only varying in length with respect to the model VS, and a needle intended for the transobturator technique. Both are supplied with the surgical instruments to aid implantation.

D. Intended Use

Safyre Slings are to be permanently implanted in women, for the treatment of stress urinary incontinence grades II and III (due to bladder hypermobility and/or Intrinsic Sphincter Deficiency) acting as a urethral support.

E. Comparison of Technological Characteristics

All of the devices are indicated for permanent implantation for the treatment of stress urinary incontinence grades II and III acting as a urethral support. All of the devices are made of the same or similar materials and are supplied with insertion instruments.

The SAFYRE VS and SAFYRE T are substantially equivalent to the predicate device. The intended use, technological characteristics of the device materials and design of the SAFYRE VS and SAFYRE T support the concept of substantial equivalence.

F. Performance Testing

Bench testing and biocompatibility testing was performed on the SAFYRE VS and SAFYRE T.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Promedon S.A.
% Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
HOPKINTON MA 01748

Re: K033691
Trade/Device Name: SAFYRE – Sling for Urinary Incontinence
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: November 22, 2003
Received: December 1, 2003

Dear Ms. Iampietro:

This letter corrects our substantially equivalent letter of December 19, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

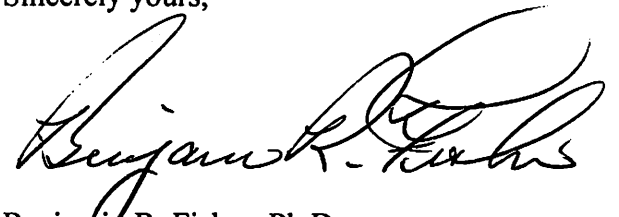
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K033691

Device Name: **SAFYRE - SLING FOR URINARY INCONTINENCE**

Indications For Use:

SAFYRE VS and SAFYRE T are to be permanently implanted in women, for the treatment of stress urinary incontinence grades II and III (due to bladder hypermobility and/or Intrinsic Sphincter Deficiency) acting as a urethral support.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson
Sign-Off
... of General, Restorative
... Neurological Devices
K033691